

### **Remarks/Arguments**

Claims 1 to 33 are pending. Claims 1 to 33 have been amended.

The Office Action stated that Claims 1 to 33 are being presented for examination.

The Office Action stated that receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

The Office Action stated that the Information disclosure statement (IDS) submitted on 11/16/2004 was filed; that the submission is in compliance with the provisions of 37 CFR 1.97 and 1.98; that, accordingly, the Examiner is considering the information disclosure statement; that there are two dates missing from the references (notation made by examiner on PTO-1449); and that appropriate correction is required.

The Office Action stated see attached copy of PTO-1449. Applicants have attached a Form PTO-1449 that includes the subject two references with dates thereof.

The Office Action stated that the following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, and 29 to 33 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Office Action stated: that a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claims does not clearly set forth the metes and bounds of the patent protection desired; see MPEP § 2173.05(c); note the explanation given by the Board of Patent Appeals and Interferences in Ex parte Wu, 10 USPQ2d

2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language; that the Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims; and note also, for example, the decisions of Ex parte Steigewald, 131 USPQ 74 (Bd. App. 1961); Ex parte Hall, 83 USPQ 38 (Bd. App. 1948); and Ex parte Hasche, 86 USPQ 481 (Bd. App. 1949). This matter has been corrected in the claims.

The Office Action stated that, in the present instance, Claims 11 and 29 to 33 recite the broad recitation against parvoviruses or picornaviruses, and the claims also recite "in particular against polioviruses" which is the narrower statement of the range/limitation. The subject claims have been amended to recite utilization against the three stated viruses in an alternative listing.

This rejection should be withdrawn.

The Office Action stated that Claims 1 to 33 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Office Action stated that Claims 1 to 33 provide for the use of a disinfectant composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicants are intending to encompass. The claims all now recite "A process" and "utilizing". The verb is an action verb that provides an active, positive step in each claim as to the actual practice of the claimed invention.

The Office Action stated that a claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. The amended claims eliminate this problem.

This rejection should be withdrawn.

Claims 1 to 33 have been rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. The amended claims eliminate this problem.

The Office Action stated see for example, *Ex pane Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). These decisions do not apply to the amended claims.

The Office Action stated to obviate these rejections, the claims should be amended to "method of use" claims; and that, for example, a method of disinfecting surfaces, instruments, etc., or a method of killing polioviruses. The amended claims are believed to eliminate this problem.

This rejection should be withdrawn.

The Office Action stated that the following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

All of the prior teachings of record must be consider under Section 103(a).

Furthermore, the invention of one prior art patent cannot be destroyed by insertion of changing elements from other prior art, or removal of vital elements from such invention – unless there is some compelling reason of record to do so.

Bellamy et al. found virucidal activity against polioviruses with a alkaline material (e.g., sodium hydroxide) and an alkyl quaternary nitrogen salt, uses aqueous composition and sometimes adds ethanol, isopropanol or n-propanol. There does not appear to be any mention of alkanolamines in Bellamy et al. Further, Bellamy et al uses a very strong basic pH of 10 to 12.

McCue et al. requires the presence of a solvent that is phenoxyalcohols and/or glycol ethers.

McCue et al. has a significantly later date than Bellamy et al.

McCue et al. are not combinable in the search for applicants' claimed invention. Without the required solvents of McCue et al., the McCue et al. system/invention is ineffective and destroyed. See Comparative Example 1 of McCue et al. Combination of McCue et al. and Bellamy et al. would result in the lose of McCue et al.'s required solvents because Bellamy et al. only uses water and sometimes ethanol, isopropanol or n-propanol. Such combination of references would destroy the McCue et al. invention so one ordinarily skilled in the art not combine, or even use, such references in the search for applicants' claimed invention. This result cannot be avoided because Bellamy et al. is prior art of record. All of the prior art teachings of record must be considered. McCue et al. cannot be used by itself because Bellamy et al. is present and its negative effect thereon cannot be ignored under Section 103(a). The obviousness rejections fail.

Claims 1 to 10 and 12 to 28 have been rejected under 35 U.S.C. 103(a) as being

unpatentable over McCue et al. (U.S. Patent No. 5,908,854) . Applicants traverse this rejection.

The Office Action stated that the claimed invention is the use of a disinfectant composition used as a virucidal agent. Applicants traverse this statement as being clearly incorrect. Applicants claim a process of using specifically-defined disinfectant compositions as a virucidal agent. The Examiner has incorrectly attempted to generify applicants' specific process.

The Office Action stated that the disinfectant composition comprises (a) an amine (Ia) or a quaternary ammonium compound (Ib) and (b) at least one alkanolamine (II), in the mass ratio 1:11 of 20:1 to 1:20. Applicants traverse this statement as being an incorrect attempt to generify applicants' specific ingredients/chemicals.

The Office Action stated that the virucidal agent is used against parvoviruses or picornaviruses, particularly against polioviruses.

The Office Action stated that McCue et al. teaches a composition effective against mycobacteria, and methods for using the composition (Abstract).

This obviousness rejection appears to be mainly (and incorrectly) based on a single sentence in the "Background Art" section of McCue et al. reading "Many marketed quaternary disinfectant compositions exhibit broad spectrum bactericidal, fungicidal and virucidal activity but they are not mycobactericidal." (Emphasis added). No prior art teaching any virucidal activity of quaternary disinfectant compositions is specifically cited in McCue et al. and the expression "quaternary disinfectant composition" merely means a composition containing a quaternary ammonium compound. No where in McCue et al. is there any teaching that the alleged virucidal activity of those unspecified compositions is caused by the quaternary ammonium compound and not by another ingredient, e.g., by a virucidal agent known in the art. McCue et al. is completely silent on the virucidal activity,

if any, of its compositions. In fact, the sentence cited by the Examiner does not support this obviousness rejection.

McCue et al. is not a relevant reference in the search for applicants' claimed invention.

The Office Action stated that the composition comprises about 0.1% wt. to about 25% wt. of a germicidal cationic quaternary compound, about 0.25% wt. to about 25% wt. of a solvent and water; and see the Abstract. All of the disclosure of a reference has to be considered by the Examiner.

As shown above, the very object of McCue et al. is to provide a composition that is effective against mycobacteria. McCue et al. states that known virucidal compositions are not effective against mycobacteria. Therefore, McCue et al. directs one ordinarily skilled in the art away from applicants' claimed invention.

The Office Action stated: that the instant Claim 1 recites limitations of the composition comprising (a) an amine (Ia) or quaternary ammonium salt (Ib) and (b) at least one alkanolamine of formula II; and that substituents for the compounds are recited. Specifically defined compounds are required by applicants' claims, not the generic approach taken by this rejection.

The Office Action stated that McCue et al. teaches quaternary ammonium compounds and salts thereof including quaternary ammonium germicides. McCue et al. teaches that known virucidal compositions are not useful against mycobacteria, McCue et al. is not a relevant reference in the quest for applicants' claimed process.

The Office Action stated: that the substituents ( $R_1$  to  $R_4$ ) of the quaternary ammonium compounds taught by McCue et al. are hydrophobic, aliphatic, aryl aliphatic or aliphatic aryl radical of from 6 to 26 carbon atoms; and see Col. 2, lines 11 to 35.

The Office Action stated: that McCue et al. teaches an alkanolamine compound, such as "mono-, di- or tri-ethanolamine"; and see Col. 4. lines 13 to 16. This is of no meaning since McCue et al. directs away from virucidal compositions.

The Office Action stated that, although McCue et al. does not specifically teach the mass ratio of quaternary ammonium compound to alkanolamine as 20:1 to 1 :20, it would have been obvious to one skilled in the art to arrive at the claimed mass ratio during the process of routine experimentation to optimize the desired virucidal or disinfectant activity. One skilled in the art has no meaning under Section 103(a), so this statement is of no support for this incorrect obviousness rejection.

The Office Action stated: that, also. McCue et al. teaches that many [known] quaternary ammonium compositions "exhibit broad spectrum bactericidal, fungicidal and virucidal activity ...,"; and see Col. 1, lines 11 to 16. McCue et al. says that they are ineffective against mycobacteria so there is no suggestion or teaching to use the McCue et al. compositions against viruses or that they would be virucidal..

The Office Action stated that, therefore, one skilled in the art would find it obvious that the instant invention would be effective as a virucidal agent. Applicants traverse this rejection as Section 103(a) deals with one ordinarily skilled in the art, not one skilled in the art.

This rejection is faulty on its face because the Examiner has not factually resolved, as is mandatory in the record the level of ordinary skill in the art.

The PTO press release of (#7 – 43) of October 10, 2007, "USPTO Publishes Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v Teleflex Decision", states:

"The Guidelines stress that the familiar factual inquires announced by the Supreme Court in its much earlier decision, *Graham v. John Deere Co.*, 383 U.S.



1, 148 USPQ 459 (1966), remain the basis for every decision regarding obviousness', noted Commissioner for Patents John Doll.

'That is, patent examiners will continue to consider (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the pertinent art, and (4) objective evidence relevant to the issue of obviousness.'"

The obviousness rejections in this Office Action, accordingly, automatically fail.

Since the independent claim is not obvious, none of the dependent claims are obvious.

The Office Action stated that instant Claim 2 recites an amine or quaternary ammonium salt selected from a group.

The Office Action stated: that McCue et al. teaches didecyl dimethyl ammonium chloride; and see Col. 3. lines 15 and 16; and would be obvious to one skilled in the art as a quaternary ammonium salt. This is meaningless – wrong standard.

The Office Action stated that, since the instant claims recite the composition comprising an amine and/or a quaternary ammonium salt, a person skilled in the art would find it obvious to recognize the didecyl dimethyl ammonium chloride taught by McCue et al. as a quaternary ammonium salt (which is part of the instant composition). Wrong standard again.

The Office Action stated: that the alkanolamine limitation of instant Claims 3 and 12 would have been obvious to one of ordinary skill in the art over the McCue et al. teaching of "an alkanolamine compound, particularly an ethanolamine such as mono-, di or tri-ethanolamine"; and see Col. 4, lines 13 to 16. This statement is in error on its face. The Examiner has not factually resolved the ordinary level of skill in the art., hence he



knows nothing about one ordinarily skilled in the art or what would be obvious to such to such a person.

The Office Action stated that the mass ratio limitation of instant Claims 4, 13, 14, and 15 would have been obvious to one of ordinary skill in the art over the McCue et al. teaching of the germicidal composition and method of using it. The Examiner cannot make any statement regarding one ordinarily skilled in the art. He does not know what is the ordinary level of skill in the art.

The Office Action stated that one skilled in the art would vary the ratio of the quaternary ammonium compound and the alkanolamine in the process of routine experimentation in order to achieve the desired virucidal or disinfectant activity. Wrong standard.

The Office Action stated: that the limitation of water as a solvent for the disinfectant composition of instant Claims 5, 16, 17, and 18 would have been obvious to one of ordinary skill in the art over the McCue et al. teaching of "compositions ...dilutable in a larger volume of water"; and see Col. 4, lines 43 to 45. Applicants traverse this statement because the Examiner has not made all of the required factual inquiries of the Graham decision.

The Office Action stated that the limitation of the composition comprising aids of instant Claims 6, 19, and 20 would have been obvious to one of ordinary skill in the art over the McCue et al. teaching of optional ingredients in the composition including "fragrances, surfactants, ... chelating agents, ...; and see Col. 4, lines 23 to 26. The Examiner has no basis for any statement re one ordinarily skilled in the art.

The Office Action stated: that the limitation of surface disinfection and instrument disinfection of instant Claims 7, 21 and 22 would have been obvious to one of ordinary skill in the art over the McCue et al. teaching of using the compositions "in a wide variety

of disinfecting applications, and in a wide variety of environments which may benefit from a disinfecting effect"; and see Col. 4, lines 51 to 53. No Graham inquiry made of ordinary skill.

The Office Action further stated: that McCrue et al. further teaches "disinfection of instruments and apparatuses, ... disinfection or decontamination of hospital environments including lavatories and lavatory fixtures, ..."; and see Col. 4, lines 55 to 64. Dependent claims are unobvious since independent claims is unobvious.

The Office Action stated that, similarly, one with ordinary skill in the art would find it obvious to use the disinfectant composition of the instant application in laundry disinfection, hand disinfection, and in chemical toilets (limitations of instant Claims 8 to 10 and 23 to 28).

This rejection should be withdrawn.

Claims 11, and 29 to 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCue et al (U.S. Patent No. 5,908,854), in view of Bellamy et al. (WO 94/22305).

The Office Action stated that the teaching of McCue et al. is stated above.

The Office Action stated that McCue et al. does not specifically teach the use of the composition against parvoviruses or picornaviruses or polioviruses. McCue et al. directs one ordinarily skilled in the art away from the use of a virucidal agent. One ordinarily skilled in the art has no reason or suggestion to look to a reference on virucidal compositions because of the teachings of McCue et al. All of the teachings of record have to be considered under Section 103(a).

Bellamy et al. does not cure the defects of McCue et al. The Office Action stated that "McCue et al. does not specifically teach the use of the composition against parvoviruses or picornaviruses or polioviruses." In fact, McCue et al. does not teach the

use of its composition against any viruses. Except for the "Background Art" section the term "virus" occurs only once (column 4, lines 38 to 40) where it is stated that "surfactants, such as nonionic ethoxylated alkylphenols may be used to enhance the membrane solubilizing capabilities of the composition. Such membrane solubilizing characteristics may be particularly advantageous in improving the transfer of the germicidal quaternary ammonium compound across the cell wall of a bacterial or virus." The compositions of the instant application do not contain ethoxylated alkylphenols and a person of ordinary skill in the art will recognize that the last part of the statement is wrong scientifically and factually since viruses do not have a cell wall.

Claim 1 is unobvious so these dependent claims are also unobvious.

One ordinarily skilled in the art would not consider Bellamy et al. to be a relevant reference.

The Office Action stated that Bellamy et al. teaches an aqueous virucidal composition suitable as hospital disinfectant, comprising alkaline material and an alkyl quaternary nitrogen salt, effective for killing polioviruses and disinfecting heat sensitive medical instruments; and see the Abstract. One ordinarily skilled in the art has no basis for paying no attention to core assertions of the later McCue et al.

The Office Action stated that Bellamy uses dialkyl dimethyl quaternary ammonium chloride as an example; and see page 5, lines 15 to 17.

The Office Action stated that a person having ordinary skill in the art at the time the invention was made would have found it obvious to combine the use of the disinfectant composition taught by McCue et al. with the virucidal (particularly against poliovirus) Bellamy et al. composition. The Examiner cannot make any statements re one ordinarily skilled in the art.

The Office Action stated: that the motivation to combine these references is provided by Bellamy et al., which demonstrates the effectiveness of the anti-viral disinfectant composition, particularly against poliovirus; and see page 8, lines 1 to 7. Both references are not relevant and McCue et al. directs away from applicants' claimed invention.

This rejection should be withdrawn.

Reconsideration and allowance of the claims are requested.

Respectfully submitted,

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